REMARKS

This Preliminary Amendment is filed contemporaneous with a Request for Continued Examination (RCE). Claims 1-21 are pending in this application. Claims 1 and 21 have been amended with this response.

Presently, claims 1-2, 4-5, 10-13 and 15-20 stand rejected under 35 U.S.C. 103(a) over Horrigan et al. (US 5,792,124) in view of Park et al. (US 6,159,187). According to the Examiner, Horrigan discloses a catheter or sheath having features in common with the claimed invention, but does not teach the use of a coil as a reinforcement means. Park was cited for its teaching of a catheter section having a "braided wire coil", as shown in Fig. 7. Applicant respectfully traverses this rejection, since neither of the cited references, either alone or in combination, teaches or suggests the use of a coil reinforcement in a flexible, kink resistant introducer sheath as claimed.

The present invention is directed to an introducer sheath. It is highly desired that an introducer sheath be flexible and resistant to kinking. These properties enable the sheath to be readily advanced through tortuous body passageways and/or directed to sensitive treatment sites. It is also desired that a sheath have as thin-walled construction as possible, consistent with its purpose. In this manner, the opening in the body for percutaneous entry may be made as small as possible, thereby minimizing trauma to the patient. Furthermore, it is desired that cost effective means be available for production of the sheath, so that the sheath can be distributed in a cost effective manner. These desirable features are present in the inventive flexible, kink resistant sheath having a coil reinforcement.

In the Declaration of Thomas A. Osborne, attached hereto, Applicant has clearly demonstrated that there are very significant differences between a braid-reinforced sheath and a coil-reinforced sheath when used in an introduce sheath. When the introducer sheath is to be used to access tortuous passages in the vasculature of a patient, a braid-reinforced sheath is prone to kinking, and thus, becoming unusable. A coil-reinforced sheath, on the other hand, is effective for resisting kinking. See, Paragraphs 6-14 of Osborne Declaration, and Exhibits A and B attached thereto.

Although Horrigan speaks in generalities about kink resistance, his use of a braid reinforcement provides inferior kink resistance when compared to a coil reinforcement. As demonstrated by the Osborne Declaration, the use of a braid reinforcement provides minimal, if any, kink resistance. In fact, the use of a braid reinforcement can actually be a cause of kinking. Osborne Declaration, Paragraph 9. A coil-reinforced sheath, on the other hand, resists kinking. (Declaration, Exhibit A).

Flexibility at the distal end is often a key feature of an introducer sheath. This is particularly true when the sheath is used to access tortuous passageways. For a sheath to be able to bend in those passageways without kinking, the sheath material on the outer part of the bend must be able to stretch, and the corresponding sheath material on the inner part of the bend must compress. The very nature of a braid (overlapping woven fibers or filaments) is such that it resists substantial expansion and compression. Merely utilizing lower durometer materials with a braid reinforcement does not overcome this deficiency. In fact, this combination largely defeats the purpose of using the lower durometer materials in the first place since it results in a tube that is only marginally more flexible. The use of a coil reinforcement, on the other hand, can elongate or increase the distance between the turns on the outside of the bend very easily with minimum force. Combining the coil reinforcement with the lower durometer distal sheath material results in a tube structure that is much more flexible and kink resistant than when a braided reinforcement is used, other things being equal.

In contrast to the beneficial property of kink resistance that is obtained when using a coil-reinforced sheath, the use of a braid reinforcement is known to provide favorable torsional control when compared to a coil (torsional control being a stated objective of Horrigan). Thus, it is clear that Horrigan was addressing problems relating to the introduction of medical devices into the body from an entirely different perspective than was the applicant herein, and his disparate solutions to those problems reflect that different direction. His invention does not adequately address the problem related to the ability of a sheath to resist kinking.

In addition to the foregoing advantage, another advantage of the use of a wire coil reinforcement in an introducer sheath when compared to a braided reinforcement is the ease of manufacture of the sheath. When a braid is utilized, it is generally necessary to fuse or otherwise

bond (at least) the ends of the braid to the inner liner. Otherwise, the high tensile strength of the braid tends to cause the braid to spring outwardly and not wrap around the liner. In addition, the terminal ends of a braid are prone to fraying. This requires the ends of the braid to be well-bonded or fused to the outer wall of the inner liner to avoid such frayed ends. A wire coil, on the other hand, may simply be compression fitted around the inner liner within the outer tube. Normally, no fusing or bonding of the coil (as in Horrigan), or its ends, is required. Osborne Declaration, Paragraph 15. As a result, the use of a wire coil reinforcement rather than a wire braid in an introducer sheath is easier to manufacture, which reduces the cost of the sheath.

In addition, as stated above, another desirable feature of an introducer sheath is that the sheath have a thin-walled construction, so that the opening in the body for percutaneous entry can be as small as possible. However, a braid-reinforced sheath has an enlarged diameter when compared to a coil-reinforced sheath, other things remaining equal. This enlarged diameter results from the crossing of the wire strands that make up the braided pattern. Thus, when reinforcing flat wire having a 0.002 inch diameter is used, the effective diameter of the windings of a coil made of such wire is 0.002 inch. Since a braid includes crossings of this flat wire, the effective diameter at the crossing points of a braid made of such wire is 0.004 inch, or twice that of the wire coil. The same relationship holds true when round wire is used, and is even more pronounced. When a key objective of such introducer sheaths is to provide a kink resistant sheath having as small an outer diameter as possible, the use of a wire coil is advantageous when compared to the use of a braid.

Notwithstanding these desirable features of a coil-reinforced sheath, Horrigan chose to utilize a wire braid as a reinforcement means in his reinforced catheter, rather than a wire coil as used in the present invention. When kink resistance and cross-sectional diameter are key considerations, such as when tortuous vascular passageways are to be traversed, the use of a coil is superior.

The patent to Park teaches a catheter section that is capable of self-forming a selected shape upon application of heat and retaining that shape upon cooling. Specifically, the catheter section includes in its wall a forming member which comprises a super-elastic nickel-titanium (nitinol) alloy. The catheter section is formed in a first shape, and is then restrained in a

polymeric outer sheath in a second shape under non-equilibrium conditions. When the polymeric outer layer is heated (and thereby softened), the catheter section re-assumes the shape given to it during the heat treatment step.

Park prefers to use super-elastic nitinol ribbon braids for reinforcement because of their ability to retain non-elastic strain and return to a prior form upon release of the polymeric restraint. Col. 7, lies 55-58. Although sheaths using super-elastic braids can be beneficial in certain defined instances, they can be complicated to use. Such sheaths require that certain known and pre-configured shapes be formed, and that certain working temperatures be used. This reference deals with the problem of accessing remote anatomical areas in a completely different, and much more complex, manner than the present invention. Although Park mentions in passing that kink-resistance is a desirable feature in catheters, he merely states the obvious. However, he does not teach or suggest the straightforward manner in which the problem is addressed in the present invention, nor does he appear to recognize the beneficial properties of a coil when compared to a braid. In fact, Park appears to prefer a braid, and more particularly, a braid formed from a super-elastic alloy, for the reasons provided in the patent.

As stated, the present invention utilizes a wire coil (rather than a wire braid), to obtain the advantages of, among others, kink resistance, small wall diameter and low manufacturing cost. The Horrigan reference neither teaches nor suggests an optimal manner of achieving such advantages, and in fact, by its use of a reinforcement braid, teaches away from such advantages. Park teaches a complex solution to the problem of access through increasingly small vessels that is very different than the present invention. Park also does not appear to recognize the problems relating to kinking that may be caused by using a braid reinforcement. Neither of these references, either individually or in combination, achieves the simple solution to the problems of kink resistance, minimizing the outer diameter, and maintaining as little expense as possible, that are achieved in the inventive sheath.

The present claims have been amended herein to even further emphasize that the claimed introducer sheath is kink resistant. Neither of the references provides any awareness of the problems solved by the present invention, nor do they provide any solution to these problems.

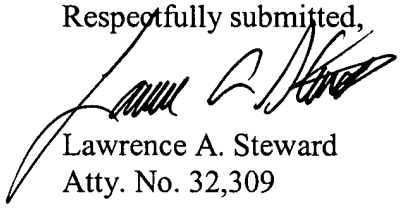
Therefore, for all of the foregoing reasons, Appellant respectfully submits that claims 1-2, 4-5, 10-13 and 15-20, as amended, are not obvious in view of the cited combination.

Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of Parker (US 5,380,384). Claims 6-9 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of Ju et al (US 5,599,325). Claim 14 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of MacDonald et al (US 6,210,396).

According to the Office Action, Parker was cited for its teaching of an inner tube having a roughed outer surface. Ju was cited for its teaching of an outer sheath tube made from a blend of a polymer and a radiopaque filler. MacDonald was cited for its teaching of an outer tube comprising first and second tube sections of different colors. Applicant respectfully submits that nothing in these teachings overcomes the shortcomings recited above with regard to the rejection of claim 1.

Based upon the foregoing, Applicant respectfully submits that all claims 1-21 are in condition for allowance. Accordingly, Applicant respectfully requests the issuance of a Notice of Allowance. If the Examiner believes that the prosecution of this application may be expedited by a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



Lawrence A. Steward
Atty. No. 32,309

LAS/cbw

BRINKS HOFER GILSON & LIONE
One Indiana Square, Suite 1600
Indianapolis, Indiana 46204
Phone: (317) 636-0886
Fax: (317) 634-6701